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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/074,272	02/14/2002	Robert K. Yang		1199-4	4926
75	90 01/04/2005			EXAM	INER
Daniel A. Scol		LAZOR, MICHELLE A			
HOFFMANN & BARON, LLP 6900 Jericho Turnpike			ART UNIT	PAPER NUMBER	
Syosset, NY 11791				1734	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/074,272	YANG ET AL.				
Office Action Summary	Examiner	Art Unit				
	Michelle A Lazor	1734				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be timed within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
Status						
<ol> <li>Responsive to communication(s) filed on <u>06 Octors</u></li> <li>This action is <b>FINAL</b>.</li> <li>Since this application is in condition for allowar closed in accordance with the practice under Exercises.</li> </ol>	action is non-final. nce except for formal matters, pro					
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Disposition of Claims						
<ul> <li>4)  Claim(s) 54,55 and 62-90 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 54,55 and 62-90 is/are rejected.</li> <li>7)  Claim(s) 87 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the conference of the c	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) □ All b) □ Some * c) ☑ None of:  1. □ Certified copies of the priority documents 2. □ Certified copies of the priority documents 3. □ Copies of the certified copies of the priorical application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive n (PCT Rule 17.2(a)).	on No d in this National Stage				
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:					

Application/Control Number: 10/074,272 Page 2

Art Unit: 1734

#### **DETAILED ACTION**

## Claim Objections

1. Claim 87 is objected to because of the following informalities: "...said active" is believed to be "...said active component". Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim if a film is first formed and then placed onto a surface having top and bottom sides. According to paragraph 44 (page 13) of the Specification, the film is formed on the surface, not before being placed on the surface. For the purpose of examination, Examiner has assumed the film is formed on the surface as described in the specification.

### Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 54, 55, 63 66, 69-71, 73, 74, 79, 80, 83, 85, 89, and 90 rejected under 35
   U.S.C. 102(b) as being anticipated by Magoon (U.S. Patent No. 4631837).

Magoon discloses a process comprising combining a water soluble cellulose derivative polymer component, such as fruit pulp, and a polar solvent such as fruit juice/water, to form a matrix with a uniform distribution of said components; forming an ingestible, self-supporting, flexible film or fruit leather when dried, from said matrix (Abstract, column 1, line 41 – column 2, line 8), said film having a uniform thickness greater than about 0.1 mils (column 3, lines 54 – 58); and drying said film by feeding said film onto a surface having top and bottom sides; said bottom side being dried first and being in substantially uniform contact with a water bath at a controlled heated temperature sufficient to dry said film (Figures 1 and 2), wherein a viscoelastic structure is formed. Since the method steps disclosed are identical to those claimed by the Applicant, it is concluded the same results would be obtained, and therefore a non-selfaggregating uniform heterogeneity of said components throughout said film would be produced. In addition, drying of said film begins as soon as the pulp and juice are placed in contact with the heated water; and said polar solvent may have a weight percent of at least 30% (column 4, line 60 – column 5, line 11). Thus Magoon discloses all the limitations of Claims 54, 55, 63 – 66, 69-71, 73, 74, 79, 80, 83, 85, 89, and 90, and anticipates the claimed invention.

#### Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Application/Control Number: 10/074,272 Page 4

Art Unit: 1734

7. Claims 62, 67, 68, 72, 78, 81, and 86 – 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 54 above, in view of Wampler et al. (U.S. Patent No. 5759599).

Magoon discloses all the limitations of Claim 54, including obtaining a uniform distribution of components wherein a specific amount of each component may be obtained from said film by cutting said film to a predetermined size since the same method steps are disclosed, thus inferring the same results would be obtained; but Magoon does not specifically disclose adding an active component, such as a flavor, to said matrix step; does not disclose said polar solvent to be a combination of water and a polar organic solvent; and does not disclose said water soluble polymer to include a starch. However, Wampler et al. disclose adding flavor, citric acid, considered a polar organic solvent, and starch to fruit leather (column 12, line 63 – column 13, line 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to add flavor, citric acid, and starch to fruit leather for enhanced quality. In addition, although Magoon does not specifically disclose dividing said film into dosage forms, it is considered obvious to one of ordinary skill in the art at the time of the invention to divide the film into substantially equal dimensions in order to distribute a measured amount of product for sale.

8. Claims 75 – 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 54 above.

Magoon does not specifically disclose reducing the weight percent of said polar solvent to about 10% or less; however, one of ordinary skill in the art at the time of the invention would Application/Control Number: 10/074,272 Page 5

Art Unit: 1734

know to reduce the amount of solvent in the final product depending on the desired final product qualities, i.e. thickness (column 3, lines 54 - 58 and column 4, lines 18 - 25).

9. Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 79 above, in view of Sharma et al. (U.S. Patent No. 6428825).

Magoon discloses all the limitations of Claim 79, but does not disclose said water insoluble polymer to include an ethyl cellulose. However, Sharma et al. disclose using an ethyl cellulose (column 3, lines 11 - 15). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use an ethyl cellulose to purify the fruit pulp slurry (column 3, lines 11 - 12).

10. Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 79 above, in view of Kubodera (U.S. Patent No. 4851394).

Magoon discloses all the limitations of Claim 79, but does not disclose said film to have a thickness of about 10 mils or less. However, it is known to produce edible films having a thickness of about 10 mils or less, as shown by Kubodera (column 9, lines 3 - 9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to produce a film having a thickness of 10 mils or less since it is well known in the art to produce thin, edible films as disclosed so that the film is minimally, if at all, sensed (column 9, lines 8 - 9).

## Response to Amendment

11. The allowability of claim 54 is rescinded in view of the above prior art references.

#### Conclusion

Art Unit: 1734

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bolland et al. (U.S. Patent No. 6047484) disclose a method for drying a thin film over a water or liquid bath (column 2, lines 23 – 56).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle A Lazor whose telephone number is 571-272-1232.

The examiner can normally be reached on Thurs - Fri 5:45 - 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MARK A. OSELE PRIMARY EXAMINER Page 6